

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION**

THIS DOCUMENT RELATES TO:

*State of California, ex rel. Ven-A-Care of the Florida
Keys, Inc. v. Abbott Laboratories, Inc., et al.*
Case No: 1:03-cv-11226-PBS

) **MDL No. 1456**
) **Master File No. 01-12257-PBS**
) **Subcategory Case No. 06-11337**
)
) **Judge Patti B. Saris**
)
) **Magistrate Judge**
) **Marianne B. Bowler**
)
)

**PLAINTIFF VEN-A-CARE OF THE FLORIDA KEYS, INC.'S REPLY TO
DEFENDANTS' JOINT BRIEF IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT**

Plaintiff-Relator, Ven-A-Care of the Florida Keys, Inc., submits this separate reply to Defendants' Joint Brief in Opposition to Plaintiffs' Motion for Partial Summary Judgment (Master Dkt # 6801). Ven-A-Care fully supports the reply brief filed concurrently by the State of California and submits this brief only to elaborate on some points at issue in Plaintiffs' Motion for Partial Summary Judgment.

It is clear after considering Defendants' opposition brief and responses to Plaintiffs' Statements of Fact that Plaintiffs have established all the elements of their liability case and that nothing that Defendants have introduced raises a genuine issue of material fact as to any of those elements. All three defendants concede that they did not report AWP's that met any reasonable plain-meaning interpretation of "average wholesale price" or prices generally and currently paid by providers for their products. To the contrary, each defendant has admitted that it generally reported and maintained AWP's that were set off of brand AWP's or sometimes a competitor's AWP. Indeed, the guts of Defendants' arguments is that they were not required to report prices that were estimates of the average net prices paid for their products. *See Responses to Dey*

Statement in Opposition to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts As to the Dey Defendants ¶¶ 8, 9-12 (Master Dkt # 6795); Mylan Statement in Opposition to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Acts As to the Mylan Defendants ¶¶ 7-12 (Master Dkt # 6800); Sandoz Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Facts As to Sandoz Inc. ¶¶ 7-12 (Master Dkt # 6794). They do not dispute the notion that they reported AWP's of \$50 while their products were being sold to pharmacy providers for \$25 or less, for example. Each of the defendants has essentially conceded the primary point made by Prof. Leitzinger in connection with Plaintiffs' Motion for Partial Summary Judgment – that their AWP's were more than 100% above the average wholesale selling price to pharmacy providers over 90 percent of the time, and more than 300% over the average price more than 65 percent of the time.¹ Accordingly, if this Court follows the reasoning in its earlier rulings and the First Circuit's ruling, and determines that the term AWP in the California Medicaid context should be interpreted according to its plain meaning, the falsity of defendants' reported AWP's is clear as a matter of law. See *In re Pharm. Indus. Average Wholesale Price Litigation*, 582 F.3d 156 (1st Cir. 2009); *In re Pharm. Indus. Average*

¹ Professor Leitzinger's calculations were made on an NDC-by-NDC basis, for each calendar year quarter during the relevant period, thus satisfying this Court's admonition that falsity must be addressed on a drug by drug basis. Other than the specific prices, there are no separate issues to address for specific drugs. Although each defendant purports to dispute Plaintiffs' SOF 24 or 25 that states Professor Leitzinger's calculation regarding the differential between reported AWP's and actual average prices, in fact the disputes are very narrow and they fail to properly dispute the gist of Prof. Leitzinger's calculations. The minor factual dispute that defendants have raised as to Prof. Leitzinger's calculations -- pertaining to the percent of the likely wholesaler markup -- is not sufficient to dispute his conclusion that the reported AWP's are substantially higher than the actual transaction prices. Precise quantification is not necessary for liability purposes where the reported prices so clearly "cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs that they are by their very nature fraudulent." *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. 2d 164, 174 (D. Mass. 2007).

Wholesale Price Litig., 460 F. Supp. 2d 277, 287 (D. Mass. 2006) (holding that “the term ‘average wholesale price’ in the Medicare statute is not a term of art for any price the pharmaceutical industry places in the industry publication and will be construed under the plain language doctrine of statutory construction”), *aff’d*, *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 170 (1st Cir. 2009); *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 143-44 (D.Mass. 2008).

Similarly, assuming that this Court applies its earlier ruling *in this case* and holds that defendants' submission of inflated prices caused the overpayments that were made by California, see *In re Pharm. Indus. Average Wholesale Price Litig.*, 478 F. Supp. at 175, there are no outstanding factual questions to be decided relating to causation and a determination as a matter of law would be warranted.² Defendants' newly-formulated intervening cause arguments can and should be rejected as a matter of law. Even assuming for purposes of this motion that defendants' presentation of California's conduct is correct and complete – which Plaintiffs vehemently dispute – that conduct simply does not constitute an intervening force that defeats the straightforward causal connection that Plaintiffs have shown between Defendants' reported prices and the overpayments made by Medi-Cal under the regulatory scheme that existed. The causal chain is simple – prices reported by defendants are published by the compendia, and then mechanically plugged into the computerized system that applies the established reimbursement algorithm to each claim submitted. Change what goes in and you change what comes out.

² Although the earlier ruling was in the context of a motion to dismiss, the predicate facts that were assumed for purposes of that ruling have now been proven (California's reimbursement methodology and its reliance upon prices reported to FDB, the reported prices and the actual average sales prices). Defendants quibble over whether FDB always promptly published precisely the AWP that they reported, but there is no genuine dispute but that the published AWPs emanated from the defendants, and that the published AWPs were used as part of the adjudication process for each claim, under the State's “lower of” formula.

Indeed, Defendants' argument is predicated on the unique and unsupportable notion that California's failure to adjust its reimbursement system was an intervening cause of the State's damages. This Court can and should reject that specious argument as a matter of law.

Further, Defendants have no actual evidence to support this argument, only speculation and hypotheses. No facts have been cited by defendants in support of a true causation-breaker – nothing to show that different AWP's submitted by any manufacturer on any given day for any given drug would not have been utilized by Medi-Cal in precisely the manner set forth in the reimbursement methodology. Defendants' argument is a conceptual argument, with no actual impact on the actual amounts that were reimbursed by Medi-Cal for the claims at issue during the relevant time period. Their arguments about all the things that might have played out differently do not affect the fact that their reported AWP's actually caused or were considered in connection with the payments that were made. There are no disputed facts that need to be resolved.

Finally, there are no genuine factual issues in dispute regarding scienter. Even if one assumes the degree of governmental knowledge and the character of the government conduct posited by the defendants, defendants have not come close to defeating Plaintiff's showing that defendants acted knowingly in reporting grossly excessive AWP's. As noted above, defendants concede that they did not report prices that complied with a plain meaning interpretation of AWP or estimated acquisition costs; they affirmatively contend that they followed a different standard. Obviously, that conduct was knowing and deliberate. Even if defendants are correct in stating that they did not intend to defraud the government, the California False Claims Act, like the federal FCA, *expressly provides that no specific intent to defraud is required.* CA. GOV'T CODE Sec. 12650(2); 31 U.S.C. § 3729(b)(1)(B). To the extent that defendants argue that the

government accepted and approved of their reported prices, they have utterly failed to make such a showing, even if one accepts their version of the facts. They have made no showing that California knew the specific nature of their misreported prices for the complaint NDCs over time; no showing of any government awareness, let alone approval, of their practice of reporting modified brand AWP as the AWP for generic products that sold for much lower prices; no showing of government approval of the actual AWP that were reported and maintained under this price reporting system, with random, substantial and often grotesque inflation over the prevailing transaction prices; and no showing of any actual reliance by defendants on any governmental directive or communiqué that would demonstrate that defendants did not act with actual knowledge, reckless disregard or deliberate ignorance as to the truth or falsity of the information that they reported.

Defendants have been given every opportunity to substantiate their arguments through exhaustive discovery, but even the facts as they misleadingly present them are not sufficient to defeat the CFCA claims. It is time for defendants to pay up for their blatant corruption of the Medi-Cal reimbursement system.

CONCLUSION

For the foregoing reasons, as well as those set forth in Plaintiffs' opening brief and the State's reply brief, Plaintiffs' Motion for Partial Summary Judgment should be granted and Defendants' motions for summary judgment should be denied.

Dated: January 15, 2009

Respectfully submitted,

THE BREEN LAW FIRM, P.A.

By: /s/ James J. Breen
JAMES J. BREEN
The Breen Law Firm, P.A.
5755 North Point Parkway, Suite 260
Alpharetta, GA 30022
Telephone: (770) 740-0008

BERGER & MONTAGUE, P.C.

By: /s/ Susan S. Thomas
SUSAN S. THOMAS
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103
Telephone: (212) 875-3000

**Attorneys for Relator,
VEN-A-CARE OF THE FLORIDA KEYS, INC.**

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on January 15, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Susan Schneider Thomas
SUSAN SCHNEIDER THOMAS